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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,777	12/29/2000	Hiroyuki Morimoto	2500.6	3913

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EXAMINER

TRAN, SUSAN T

ART UNIT PAPER NUMBER

1615

DATE MAILED: 02/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No. **09/647,777**

Applicant(s) **Morimoto et al.**

Examiner **Susan Tran**

Art Unit **1615**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

Receipt is acknowledged of applicant's Declaration filed 12/29/00, Preliminary Amendment A filed 12/29/00, and Corrected Filing Receipt filed 04/23/01.

#### *Claim Rejections - 35 U.S.C. § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "shape of the tablet is anomalous" in claim 22 is vague because the metes and bounds of the patent protection desired are unascertainable. It is suggested to amend the phrase to a specific shape, or further clarification is requested.

Claim 23 recites the phrase "average disintegrating time or average elution time" is indefinite because the metes and bounds of the patent protection desired are unascertainable. It is suggested to further clarify "average disintegrating time or average elution time".

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***Claim Rejections - 35 U.S.C. § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-20, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsushima et al. US 6,036,974.

Tsushima teaches a method for preparation of molded tablet comprising spray coat of lubricant to the punch (see steps A-D, columns 4-7; and examples 1-7). The tableting mixture comprising of medicines (active agents), binder, excipient, and wetting agent (column 4, lines 23-31). The lubricant to be coated on the surface of the tablet comprising magnesium stearate or talc (column 6, lines 51-62). Tsushima does not teach the percent weight of the lubricant coated on the surface of the tablet, however, since the claimed percent weight of the lubricant is so low, e.g., 0.0001%, it would have been obvious for one of ordinary skill in the art to by, routine experimentation determine a suitable amount of lubricant to obtain a smooth surface tablet having the desire hardness, and disintegration times.

3. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over .

Tsushima is relied upon for the reasons stated above. The reference is silent as to the dividing line on the tablet. However, the dividing line, groove line, marking line, or scored tablet

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is well known in the art, therefore, it would have been obvious for one of ordinary skill in the art to, by routine experimentation prepare a scored tablet, or tablet with dividing line.

4. Claims 1-14, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsushima et al., and Morimoto et al. EP 650 826 A1

Tsushima is relied upon for the reasons stated above. Tsushima does not teach lubricant is being sprayed in a spraying chamber mixed with pulsating vibration air.

Morimoto teaches a rotary type tableting machine with lubricant spraying means comprising discloses in column 2, lines 31-58. Thus, it would have been obvious for one of ordinary skill in the art to modify Tsushima's method using the spraying chamber mixed with pulsating vibration air. The reason for this modification is to obtain method suitable for molding tablet useful in pharmaceutical art.

#### *Pertinent Arts*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vilkov, and Jain are cited as being of interest for the teaching of tablet containing coated lubricant.

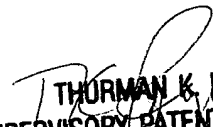
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*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thorman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
THORMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600